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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/004,381      | 10/31/2001  | Jack W. Szostak      | 00786/388002        | 7263             |

21559 7590 09/23/2003

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EXAMINER

SNEDDEN, SHERIDAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1653     | 10           |

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                    |                |
|------------------------------|--------------------|----------------|
| <b>Office Action Summary</b> | Application No.    | Applicant(s)   |
|                              | 10/004,381         | SZOSTAK ET AL. |
|                              | Examiner           | Art Unit       |
|                              | Sheridan K Snedden | 1653           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14 and 17-19, drawn to a peptide that binds streptavidin, classified in class 530, subclass 350.
  - II. Claims 15-16 and 20-22, drawn to nucleic acids encoding a peptide and vector, classified in class 435, subclass 69.1.
  - III. Claims 23, drawn to a method of purifying a protein, classified in class 530, subclass 412.
  - IV. Claim 24-27, drawn to a method of detecting the presence of a fusion protein, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention II are related to the protein of invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the claims of invention II. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein product could be made recombinantly or chemically synthesized.

Invention IV discloses a method for detecting the product of invention I and are thus related. However, the inventions are patentably distinct because the product of invention I need not be present during the detection process and thus the method of invention IV can neither utilize the products of invention I nor be used to make such products.

The product of invention II is not used in the method of inventions III or IV. Therefore, invention II is patentably distinct from inventions III or IV.

The methods of inventions III and IV require different products and steps and have different endpoints. Therefore, inventions III and IV are patentably distinct.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-IV, restriction for examination purposes as indicated is proper.

***Advisory Information***

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
September 12, 2003

SKS

*Karen Cochrane Carlson RDS*  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER